510(k) SUMMARY

K030789

MAR 2 6 2003

Submitter Information
Lori Haller
STERIS Corporation
Manager, Regulatory Affairs
2424 West 23rd Street
Erie, Pennsylvania 16506
(814) 870-8559
Date Summary Prepared: March 10, 2003

Introduction

The Amsco Century Steam Sterilizer is a Class II medical device as defined by 21 CFR 880.6880. This sterilizer is intended for the terminal sterilization of non-porous and porous, heat and moisture-stabile materials used in healthcare facilities. The Amsco Century Steam Sterilizer is substantially equivalent with the predicate device Eagle Century Steam Sterilizer, K964332, cleared June 1, 1998 and also substantially equivalent to Castle 400HC/500HC Series Steam Sterilizer, K012573, cleared September 5, 2001 for the 135°C (275°F) for 3 minutes prevac cycle claim.

The Amsco Century *Prevacuum* Steam Sterilizer (16" x 16" x 26" and 20" x 20" x 38") is equipped with the following factory-programmed sterilization cycle values:

Prevacuum Configuration

Cycle	Recommended Loads	Sterilize Temp	Sterilize Time	Dry Time
Flash	Unwrapped instrument tray with a single instrument	270°F (132°C)	3 minutes	1 minute
Flash	Unwrapped instrument tray with multiple non-porous instruments, maximum weight 17 pounds per tray.	270°F (132°C)	10 minutes	1 minute
Express	Single wrapped instrument tray with a single instrument. Non-porous goods only.	270°F (132°C)	4 minutes	3 minutes
Prevac	Up to two double wrapped instrument trays, maximum weight 17 pounds per tray. Up to six fabric packs.	270°F (132°C)	4 minutes	20 minutes[1]
Prevac	Up to two double wrapped instrument trays, maximum weight 17 pounds per tray.	275°F (135°C)	3 minutes	16 minutes

[1]Five minute dry time can be used for processing a single fabric pack.

The Amsco Century *Gravity* Steam Sterilizer (16" x 16" x 26" and 20" x 20" x 38") is equipped with the following factory-programmed sterilization cycle values:

Gravity Configuration

Cycle	Recommended Loads	Sterilize Temp	Sterilize Time	Dry Time
Flash	Unwrapped instrument tray with a single instrument	270°F (132°C)	3 minutes	1 minute
Flash	Unwrapped instrument tray with multiple non-porous instruments, maximum weight 17 pounds per tray.	270°F (132°C)	10 minutes	1 minute
Gravity	Up to two double wrapped instrument trays, maximum weight 17 pounds per tray.	270°F (132°C)	15 minutes	30 minutes
Gravity	Fabric Packs up to six fabric packs	250°F (121°C)	30 minutes[2]	15 minutes

[2]A 270°F (132°C) cycle adjusted to 25 minute Sterilize Time can be used for processing fabric packs.

Effectiveness
Effectiveness of sterilizer function and exposure time recommendations is demonstrated by complete kill of biological indicators and by verifying an appropriate safety factor that is a sterility assurance level (SAL) or probability of surviving micro-organism that is no greater than 10^{-6}. STERIS validates its sterilization cycles using recommended practices, standards and guidelines developed by independent organizations such as the Association for the Advancement of Medical Instrumentation (AAMI). The Amsco Century 135°C (275°F) for 3-minute prevac steam sterilization cycle was validated to meet the requirements of ANSI/AAMI ST8:2001, "Hospital Steam Sterilizers", November 11, 2001.

Safety
STERIS sterilizers including the Amsco Century Steam Sterilizers have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Amsco Century Steam Sterilizer complies with the following requirements:

- Underwriters Laboratory (UL) Electromedical Code 3101 as certified by Intertek Testing Services (ITS).
- Canadian Standards Association (CSA) Standard C22.2 No. 1010-1 as certified by Intertek Testing Services.
- American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels.

Hazards – Failure of Performance
Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected prior to the incident.

To avoid failure, the user must ensure that the materials, instruments and devices to be sterilized are thoroughly cleaned, the manufacturer's instructions for use are followed, the cycle to be used for each type of sterilizer load has been validated, the sterilizer has been maintained in accordance with the sterilizer manufacturer's recommended maintenance schedule and is operating properly, and each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

Today, there are many steam sterilizers in daily use in hospitals throughout the United States. The incidence of sterilizer malfunction or sterilization process failure is relatively rare. Further, there are no known reports in the literature of patient infections that have resulted from steam sterilizer failures. The technology designed into STERIS steam sterilizers including the Amsco Century Steam Sterilizer provides microprocessor controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

User Information
STERIS conducts in-house training and has developed a series of user training videos that provide helpful information about the appropriate use of steam sterilizers. STERIS further provides information to the user that is intended to ensure safe and effective use of steam sterilization in its detailed Operator Manual and other labeling. STERIS also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in health care facilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2003

Ms. Lori A. Haller
Manager, Regulatory Affairs
Steris Corporation
2424 West 23rd Street
Erie, Pennsylvania 16506

Re: K030789
Trade/Device Name: AMSCO Century Steam Sterilizer
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: March 11, 2003
Received: March 12, 2003

Dear Ms. Haller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name:
Amsco Century Steam Sterilizer

Indications for Use:
The Amsco Century Steam Sterilizer is designed for efficient sterilization of non-porous and porous, heat and moisture-stabile materials used in healthcare facilities. The Amsco Century Steam Sterilizer is available in the following configurations:

16" x 16" x 26" Single Door Gravity*	16" x 16" x 26" Single Door Prevacuum
16" x 16" x 26" Double Door Gravity	16" x 16" x 26" Double Door Prevacuum
20" x 20" x 38" Single Door Gravity	20" x 20" x 38" Single Door Prevacuum
20" x 20" x 38" Double Door Gravity	20" x 20" x 38" Double Door Prevacuum

*Note: No changes are being made to the gravity sterilizers program.

The Amsco Century Steam Sterilizer is equipped with the following factory-programmed set sterilization cycle values:

Prevacuum Configuration

Cycle	Recommended Loads	Sterilize Temp	Sterilize Time	Dry Time
Flash	Unwrapped instrument tray with a single instrument	270°F (132°C)	3 minutes	1 minute
Flash	Unwrapped instrument tray with multiple non-porous instruments, maximum weight 17 pounds per tray.	270°F (132°C)	10 minutes	1 minute
Express	Single wrapped instrument tray with a single instrument. Non-porous goods only.	270°F (132°C)	4 minutes	3 minutes
Prevac	Up to two double wrapped instrument trays, maximum weight 17 pounds per tray. Up to six fabric packs.	270°F (132°C)	4 minutes	20 minutes[1]
Prevac	Up to two double wrapped instrument trays, maximum weight 17 pounds per tray.	275°F (135°C)	3 minutes	16 minutes

[1]Five minute dry time can be used for processing a single fabric pack.

Gravity Configuration

Cycle	Recommended Loads	Sterilize Temp	Sterilize Time	Dry Time
Flash	Unwrapped instrument tray with a single instrument	270°F (132°C)	3 minutes	1 minute
Flash	Unwrapped instrument tray with multiple non-porous instruments, maximum weight 17 pounds per tray.	270°F (132°C)	10 minutes	1 minute
Gravity	Up to two double wrapped instrument trays, maximum weight 17 pounds per tray.	270°F (132°C)	15 minutes	30 minutes
Gravity	Fabric Packs up to six Fabric Packs	250°F (121°C)	30 minutes[2]	15 minutes

[2]A 270°F (132°C) cycle adjusted to 25 minute Sterilize Time can be used for processing fabric packs.

(Please Do Not Write Below This Line – Continue on Another Page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____
(Per 21 CFR 801.109)

OR

Over-the-counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030789